

Assisted Human Reproduction Canada

2008-2009

Departmental Performance Report

The Honourable Leona Aglukkaq
Minister of Health

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Minister's Message

I am pleased to present Assisted Human Reproduction Canada's Departmental Performance Report for 2008-2009.

Assisted Human Reproduction Canada (AHRC) commenced operations in early 2007 to protect and promote the health, safety, dignity and rights of Canadians who use or are born of assisted human reproduction (AHR) technologies, and to foster the application of ethical principles in their use and development.



Establishing a regulatory agency, especially in the complex and quickly evolving field of assisted human reproduction, requires careful planning. In the past year, the Agency continued to seek as many perspectives as possible to inform its work of ensuring the safety and ethics of AHR activities and research in this country.

By consulting and collaborating with stakeholder groups, and monitoring developments in AHR scientific practices and international trends, the Agency continued to develop and refine the infrastructure and networks that support the delivery of its mandate.

This rigorous groundwork is key to building the Agency's capacity for safeguarding the health and safety of Canadians who use reproductive technologies to build their families; its meticulous and inclusive approach to fulfilling its responsibilities will benefit all Canadians affected by or interested in assisted reproduction.

The Honourable Leona Aglukkaq
Minister of Health

President's Message

With increasing frequency, national and international media reports are telling the stories of people around the world affected by the use of assisted human reproductive technologies and new developments in this field. These reports confirm what we at Assisted Human Reproduction Canada already know: while these technologies offer hope to many families, their complexity also requires regulators, practitioners and users to be mindful of the associated risks and implications of evolving practices.

To provide effective leadership in this rapidly changing area of human activity, the Agency must be in close contact with its various stakeholders. Consequently, outreach and collaboration were at the heart of the Agency's initiatives in the past year.



In our exchanges with policy makers, practitioners, researchers, AHR patients, offspring and interested Canadians, the Agency continued to seek input on the risks and opportunities for those who use and are born of assisted human reproduction technologies. The Agency consulted broadly on the scientific, legal and social considerations of oversight agencies, and continued to monitor international AHR activities and standards.

In anticipation of the development of additional regulations by Health Canada, the Agency also solidified its plans and priorities for research, monitoring and compliance activities that will support the delivery of its mandate as the federal regulatory agency in the field of reproductive technologies.

I am pleased with the progress made in strengthening the Agency's relationships, systems and resources over the past year. Canadians will continue to benefit from the Agency's careful and collaborative approach to building a professional and transparent agency to serve those who use and are born of assisted reproductive technologies.

Dr. Elinor Wilson
President

SECTION 1: AGENCY OVERVIEW

1.1 Summary Information

Raison d'être

The Assisted Human Reproduction Agency of Canada (AHRC) was established in 2006 under the authority of the *Assisted Human Reproduction Act* (AHR Act). The Act seeks to protect and promote the health, safety, dignity and rights of those who use assisted human reproduction (AHR) technologies; prohibits unacceptable activities, such as human cloning, sex-selection or commercialization of human reproductive capabilities; and places control over AHR-related research.

Responsibilities

AHRC is the federal regulatory agency responsible for protecting and promoting the health, safety, dignity and rights of Canadians who use or are born of assisted human reproductive technologies.

The Agency is also responsible for fostering an environment in which ethical principles are applied in all matters relating to assisted human reproduction, while allowing scientific advances that benefit Canadians.

AHRC's mandate and responsibilities are set out in the AHR Act. The Agency's key responsibilities include:

- Implementing and administering a licensing framework for controlled activities, including AHR procedures and related research;
- Developing an inspection strategy to ensure compliance with the AHR Act and its regulations;
- Developing and maintaining a national Personal Health Information Registry (PHIR) on AHR that can become a key component of a more comprehensive AHR health surveillance strategy;
- Becoming a centre of expertise on AHR by collecting and disseminating public information;
- Communicating with and engaging stakeholders on AHR issues; and
- Advising the Minister of Health on AHR issues.

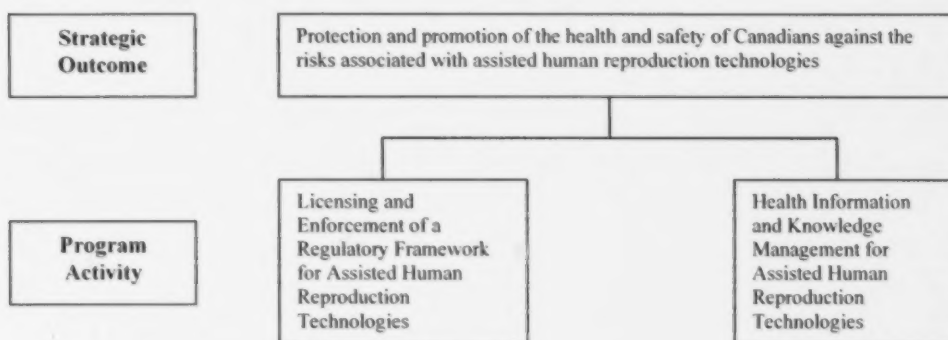
Strategic Outcome

In order to effectively pursue its mandate, the Agency aims to achieve the following strategic outcome:

Protection and promotion of the health and safety of Canadians against the risks associated with assisted human reproduction technologies.

Program Activity Architecture

The chart below illustrates Assisted Human Reproduction Canada's complete framework of program activities, which roll up and contribute to progress toward the Agency's strategic outcome.



1.2 Performance Summary

Financial Resources

(\$ thousands)

Planned Spending	Total Authorities	Actual Spending
12,418	12,418	5,289

The total authorities were \$12.4 million, due partly to re-profiling of unspent funds from previous years prior to the establishment of the Agency. Actual spending was \$5.3 million. The spending shortfall was as a result of the incremental implementation of the Agency's mandate, in parallel with the development of the regulations by Health Canada.

Human Resources
(FTEs)

Planned	Actual	Difference
44	16	28

Significant progress was made during the year on staffing. Staffing was undertaken at a pace consistent with the incremental implementation of the Agency's mandate.

Strategic Outcome 1: Protection and promotion of the health and safety of Canadians against the risks associated with assisted human reproduction technologies

Performance Indicator	Targets	2008-09 Performance
*As the regulations come into force, develop operational guidelines to administer the <i>Assisted Human Reproduction Act</i> and its associated regulations.	*In advance of the regulations coming into force: • Develop the groundwork to implement a licensing framework for controlled activities and Personal Health Information Registry. • Develop an inspection strategy to ensure compliance with the AHR Act and regulations. • Develop and progressively implement a stakeholder outreach strategy and information dissemination plan.	The Agency made considerable progress in developing the systems, policies and procedures necessary to implement a licensing and inspection framework for activities related to assisted human reproduction in Canada. It also worked in collaboration with key stakeholders to refine its capacity to collect, store and analyze information to be contained in the Personal Health Information Registry. With an interim compliance and enforcement strategy in place, the Agency undertook to educate and collaborate with other enforcement and accreditation agencies, while continuing to respond to allegations of violation and to monitor compliance with Section 8 of the AHR Act. Finally, it increased its outreach efforts on a number of fronts, by establishing an expert science advisory panel, initiating international information exchanges, collaborating with national organizations working in AHR, and launching a comprehensive website for the benefit of all Canadians interested in or affected by reproductive technologies.

*The performance indicator and targets at the strategic outcome level have been incorporated from the approved Departmental Performance Measurement Framework (December 2008) and the 2009-10 Report on Plans and Priorities.

Program Activity	2007-08 Actual Spending (\$ thousands)	2008-09				Alignment to Government of Canada Outcomes
		Main Estimates	Planned Spending	Total Authorities	Actual Spending	
Licensing and Enforcement of a Regulatory Framework for Assisted Human Reproduction Technologies.	3,051	7,803	7,803	7,803	2,803	☞ <u>Healthy Canadians</u>
Health Information and Knowledge Management for Assisted Human Reproduction Technologies.	1,847	4,615	4,615	4,615	2,486	☞ <u>Healthy Canadians</u>

Contribution of Priorities to Strategic Outcomes

Operational Priorities	Type	Status	Linkages to Strategic Outcomes
1. To protect and promote the health and safety of Canadians who use, and offspring who are born of, AHR technologies.	Ongoing	Mostly met (within current regulatory framework). See performance summary for Strategic Outcome 1.	Strategic Outcome 1 Will ensure Canadians using AHR technologies are aware of and protected from the associated risks.
2. To contribute to the development of Health Canada's AHR regulations.	Intermediate term	Met all AHRC actively contributed to Health Canada's regulatory development process.	Strategic Outcome 1 Will provide necessary authority to protect and promote health and safety of Canadians by enforcing compliance with regulations.
3. To increase the awareness of Canadians and health professionals about AHR and the Agency's role.	Ongoing	Mostly met See performance summary for Strategic Outcome 1.	Strategic Outcome 1 Protects the health and safety of Canadians by providing them with information to make informed decisions about AHR technologies, and the Agency's role in regulating AHR practices.

Management Priorities	Type	Status	Linkages to Strategic Outcomes
1. To create the capacity in AHRC to implement the regulations.	Intermediate term	Somewhat met See performance summary for Strategic Outcome 1.	Strategic Outcome 1 To protect and promote health and safety of Canadians, the Agency must have adequate resources and systems to enforce compliance with AHR regulations.
2. To develop the tools to disseminate information on AHR.	Ongoing	Mostly met See performance summary for Strategic Outcome 1.	Strategic Outcome 1 Will better promote the health and safety of Canadians by providing them with more accessible information to make informed decisions about AHR technologies, and the Agency's role in regulating AHR practices.

Risk Analysis

AHRC has been actively monitoring and managing its risks since the Agency was established. It recently launched a systematic review of its risks to fully document its plans to manage those risks, and to integrate a risk monitoring and reporting process into its planning cycle. This will serve as the Agency's interim corporate risk management framework, which will be updated and revised as the full regulatory framework is implemented.

Few fields are changing faster than assisted human reproduction. Each technological innovation brings with it health, ethical, social and economic implications. AHRC is putting in place the resources and mechanisms to enable it to keep abreast of a rapidly changing environment, in terms of both science and international developments. One such mechanism is the recently established Science Advisory Panel, which brings together recognized experts in the field.

As a new Agency, AHRC is working to put in place the infrastructure (i.e., policies, procedures and systems) to effectively and efficiently manage its operations, as well as the specialized systems that will be required to implement the regulatory process once the regulations come into force. The Agency is implementing an information management framework that will ensure the continuity and safeguarding of corporate information, currently and when the move of operations to the Agency headquarters in Vancouver is completed. The systems that will be required to administer the regulations and Personal Health Information Registry are being developed on a task-based and modular basis, using a best-practices approach to ensure operational alignment with the regulations being developed by Health Canada. Specialized resources are being retained to ensure the appropriate analysis and safeguarding of the personal health information the Agency will eventually be collecting.

From the outset, AHRC has recognized the importance of collaborating with various stakeholder groups to deliver on its mandate. The Agency worked on the development of a comprehensive stakeholder outreach strategy that will build on its successful efforts to identify and ensure appropriate engagement of stakeholders. Fostering public and stakeholder awareness and understanding will be key to successfully meeting Agency objectives.

Resource planning is a challenge for the Agency, as it must take into account the completion of the establishment of the organization, the anticipated timing of the regulations coming into force, and plans to complete the move of operations to Vancouver. A human resources strategy was developed, key positions were staffed with indeterminate employees, and integrated business and human resource plans are being reviewed and updated on a regular basis.

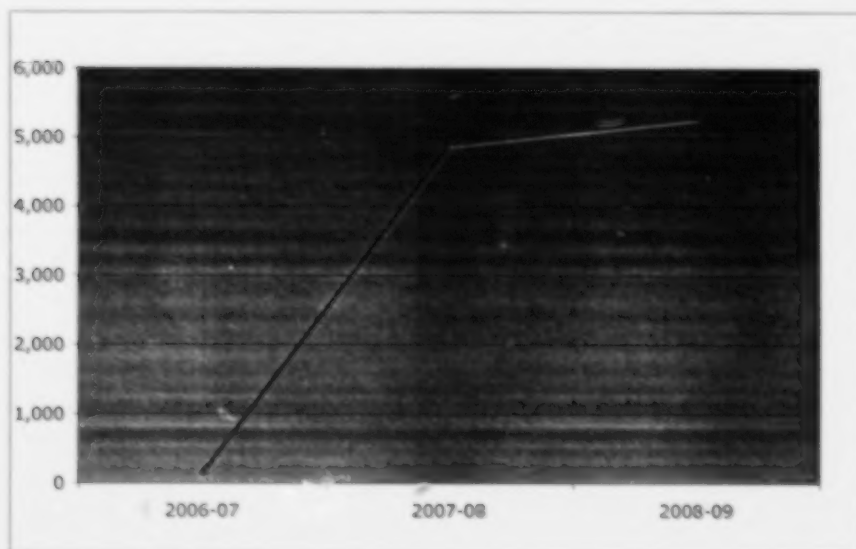
Expenditure Profile

Spending Trends

AHRC spent \$5.3 million to meet the expected results of its program activities and contribute to its strategic outcome in 2008-09.

The figure below illustrates the Agency's spending trend from 2006-07 to 2008-09.

Spending Trend



AHRC began operations in February 2007, and spending over its first few months of existence in 2006-07 totalled \$134,000. In 2007-08 and 2008-09, AHRC's spending increased to \$4.9 million and \$5.3 million respectively, as the Agency has been fit up, staff have been hired and the infrastructure necessary to fulfill its mandate has been put in place.

Voted and Statutory Items

(\$ thousands)

Vote # or Statutory Items (S)	Truncated Vote or Statutory Wording	2006-07 Actual Spending	2007-08 Actual Spending	2008-09 Main Estimates	2008-09 Actual Spending
15	Operating expenditures.	130	4,616	11,783	4,932
(S)	Contributions to employee benefit plans.	4	282	635	357
	Total	134	4,898	12,418	5,289

Parliament approved resources of \$12.4 million for the Agency, as per its Report on Plans and Priorities for 2008-09. The Agency's total actual spending for 2008-09 was \$5.3 million.

The only statutory item for AHRC pertains to contributions to employee benefit plans in the amount of \$357,195.

SECTION 2: ANALYSIS OF PROGRAM ACTIVITIES BY STRATEGIC OUTCOME

2.1 Strategic Outcome 1: Protection and Promotion of the Health and Safety of Canadians against the Risks Associated with Assisted Human Reproduction Technologies

2.1.1 Program Activity: Licensing and Enforcement of a Regulatory Framework for Assisted Human Reproduction Technologies

2008-09 Financial Resources (\$ thousands)			2008-09 Human Resources (FTEs)		
Planned Spending	Total Authorities	Actual Spending	Planned	Actual	Difference
7,803	7,803	2,803	22	7	15

Program Activity Summary

Expected Results	Performance Indicators	Targets	Performance Status	Performance Summary
An effective and efficient licensing and inspection framework.	Once the regulations are passed, a documented licensing and inspection framework which is communicated to clinics and stakeholders and which sees inspections carried out on a basis consistent with the framework.	Develop guidance documents, administrative policies and electronic tracking systems for the licensing and inspection of AHR clinics and facilities.	Somewhat met	- It is important to note that publishing of draft regulations under the AHR Act is being deferred by Health Canada until after the Supreme Court of Canada releases its opinion on constitutional issues related to the AHR Act. - Building on its interim compliance and enforcement strategy, which addresses compliance with respect to the prohibitions and controlled activities of the AHR Act, the Agency defined business requirements for controlled activity and premises licenses and initiated license application design work. - AHRC formalized its process for dealing with allegations of violation of the AHR Act and regulations, through its Memorandum of Understanding (MOU) with the Health Canada Inspectorate. - In accordance with this process, the Agency responded to all allegations brought to its attention. It also initiated and completed an assessment of AHR clinic compliance with Section 8 of the AHR Act and its regulations. - Through interactions with other Health Portfolio partners, AHRC identified best practice regulatory database models that may be customized for AHRC's system infrastructure.

Expected Results	Performance Indicators	Targets	Performance Status	Performance Summary
A well-informed and engaged stakeholder community.	Communication of the framework to the stakeholders by various means including direct contact, presentations at professional forums, literature and electronic means such as a website.	Participate in or support key stakeholder groups, professional associations, colleges, and licensing and accreditation bodies in the development of other relevant supporting policy instruments (e.g., standards, national guidelines, accreditation models, etc.).	Mostly met	• AHRC continued to build productive relationships with stakeholders, through AHRC-sponsored working groups, formal and informal presentations. • AHRC began collaborating with several partners, including Accreditation Canada, to develop an integrated inspection and accreditation model to minimize administrative burden on regulated parties. • AHRC continued to support and participate in working groups of the Canadian Fertility and Andrology Society (CFAS) and Canadian Standards Association (CSA) to develop national guidelines for AHR. • AHRC made several formal presentations on its mandate, regulatory role and activities for stakeholders and AHR clinics.
	Implement a research agenda pertaining to AHR.	Partner with Canadian Institutes for Health Research (CIHR) to ensure research pertaining to AHRC's mandate is conducted in a timely, rigorous, transparent and cost-effective manner.	Met all	• AHRC co-hosted an expert workshop with CIHR to develop a national research agenda for AHR. • AHRC also partnered with CIHR in an AHR knowledge transfer initiative and to plan for the launch of a research funding opportunity on psychosocial issues related to AHR. • AHRC officials attended CIHR meetings of the Stem Cell Oversight Committee, National Cohort Studies and Health Gametes workshops.

Benefits for Canadians

Through this program activity, AHRC contributes to a "Whole of Government" approach to fostering Healthy Canadians. Specifically, the Agency protects the health and safety, dignity and rights of Canadians using AHR technologies by monitoring compliance with the AHR Act and its regulations.

Performance Analysis

While Health Canada's development of regulations and policies continued, this work was affected by an opinion of the Quebec Court of Appeal on the constitutionality of certain provisions of the AHR Act. The Government of Canada appealed that opinion to the Supreme Court of Canada and decided not to pre-publish regulations while the constitutional issues were before the Court. In the interim, AHRC directed its efforts to meeting those targets within its control. It continued to solicit, assess and compare advice and models from its counterparts and stakeholders in order to build an effective and appropriate framework for licensing and inspection of AHR clinics and facilities across the country.

The Agency also initiated new relationships with stakeholder groups and Canadian licensing and accreditation bodies, while continuing to support and collaborate with medical associations, to encourage the incorporation of as much expertise and as many perspectives as possible in the development of national guidelines for assisted human reproduction. Finally, it worked to ensure that all other associated systems and resources needed to deliver on its current operational priorities were in place.

Lessons Learned

As AHRC awaits further regulations necessary to give effect to key elements of the *Assisted Human Reproduction Act* that give it the authority to implement and enforce the legislation's provisions, the Agency continued to consult with key stakeholder groups and associations in order to incorporate best practices from other jurisdictions, compliance and enforcement agencies, and accreditation bodies into the licensing and inspection policies and procedures related to assisted human reproduction.

2.1.2 Program Activity: Health Information and Knowledge Management for Assisted Human Reproduction Technologies					
2008-09 Financial Resources (\$ thousands)			2008-09 Human Resources (FTEs)		
Planned Spending	Total Authorities	Actual Spending	Planned	Actual	Difference
4,615	4,615	2,486	22	9	13

Program Activity Summary

Expected Results	Performance Indicators	Targets	Performance Status	Performance Summary
A Personal Health Information Registry that complements an eventual AHR surveillance network	Develop a Personal Health Information Registry that is integrated into an overall surveillance network, once the regulations are developed	Develop a Personal Health Information Registry that may function as a component of a broader AHR surveillance network	Somewhat met	- Worked with Health Canada to develop the regulations that will specify the health reporting information required to be collected and maintained by the Agency in the Personal Health Information Registry (PHIR). - AHRC continued to refine the business requirements for the systems and databases required for the Personal Health Information Registry through broad and inclusive consultation with key stakeholders. - AHRC engaged the Canadian Fertility and Andrology Society (CFAS), to review, evaluate and make recommendations to improve its collection of treatment cycle information provided voluntarily by Canadian fertility centres using assisted reproduction technology. The aim is to provide high quality reporting information on assisted reproduction technology activities in Canada to meet AHRC's regulatory requirements once the regulations come into force. - AHRC also engaged CFAS and other stakeholders in the identification of measures that would inform health surveillance related to assisted reproduction technology.
Access to information about assisted human reproduction by policy makers, health professionals, parents,	Establish a Science Advisory Panel.	Establish a Science Advisory Panel that can provide AHRC with value-added council and advice in relation to	Met all	A 13-member Science Advisory Panel (SAP) was established to provide ongoing and timely advice to AHRC's Board of Directors on current and emerging research and science issues relating to AHR and embryo research in Canada and internationally, including diagnostic and treatment options, new technologies, and standards and

Expected Results	Performance Indicators	Targets	Performance Status	Performance Summary
children born of AHR procedures, researchers and the Canadian public.		advances and emerging scientific issues related to AHR.		procedures. • Chaired by Dr. John Collins, an internationally recognized AHR authority, the SAP is comprised of world-renowned experts in the field of AHR research, with representatives from basic and social science as well as clinical researchers from leading Canadian and American universities. • The SAP developed its work plan and priorities, as well as a process to deal with innovative practice and future scanning for developments in the AHR field.
	Engage in direct contact with counterpart international AHR agencies.	Liaise with counterpart AHR agencies around the world with a view to sharing best practices and encouraging common approaches to regulating the safety and effectiveness of AHR consistent with ethical principles.	Met all	• AHRC hosted the first invitational International Forum on Cross-Border Reproductive Care in Ottawa in January 2009. More than 50 delegates, including regulators from Australia, India, Belgium, the United Kingdom, the European Commission, France and Italy, attended the working meeting. The goal of the forum was to share experiences and build agreement among participating countries and organizations on the principles underpinning safe, quality care when patients seek and obtain reproductive care outside the country in which they reside. • AHRC negotiated a staffing interchange agreement with the UK's Human Fertilisation and Embryology Authority (HFEA) to provide an operational perspective of the HFEA licensing and inspection model.
	Create an AHRC website and other tools to disseminate information.	Develop and maintain a website with relevant information for patients, providers, practitioners and children born of AHR.	Met all	• The AHRC website was launched in September 2008, with work ongoing to enhance the information offerings. • The Agency also established a contact email and 1-800 number to respond to any questions or concerns from the public.
	Increase the flow of information on AHR to stakeholders and public via	Provision of information for health professionals and the public on AHR	Met all	• AHRC promoted the engagement of stakeholders and research community members in undertaking and communicating results of findings on topics such as incidence of multiple births and the implications of the use of

Expected Results	Performance Indicators	Targets	Performance Status	Performance Summary
	a range of outreach vehicles and partnerships.	matters or issues via newsletters, presentations at conferences, annual reports, brochures and reports in journals.		AHR technologies at conferences, seminars and academic forums. • The Tripartite Committee, composed of representatives from AHRC, Canadian Fertility and Andrology Society (CFAS) and Society of Obstetricians and Gynaecologists of Canada (SOGC), met regularly to share information and make recommendations to respective organizations on current and future initiatives. • An editorial committee was established with representatives from different stakeholder groups to help AHRC identify information needs and ensure effective messages. • Two newsletters and an annual report were developed and disseminated to stakeholders, providing information on AHRC's activities and AHR matters. • Two patient information pamphlets were produced and distributed, one regarding the AHR Act, the second on genetic counselling, produced in partnership with the Canadian Association of Genetic Counsellors (CAGC).
	Increase the coordination and collaboration on AHR issues across jurisdictions.	Work collaboratively with the provinces and territories to identify and reconcile issues of common concern and develop an effective, efficient and seamless AHR regime that protects the health and safety of all Canadians and children born of AHR.	Somewhat met	• AHRC initiated exchanges with provincial and territorial vital statistics and family law officials. • AHRC also held discussions with CFAS about the harmonization of data collection pertaining to assisted reproduction technology.

Benefits for Canadians

The eventual establishment of a Personal Health Information Registry (PHIR) will be critical for monitoring and improving the safety and effectiveness of AHR procedures. The registry will also provide a valuable resource to children born of reproductive technologies to enable them to find out about their medical and genetic information. The PHIR will eventually become a key component of a larger AHR health surveillance system capable of providing information needed to determine health outcomes relating to persons undergoing certain AHR procedures and children born as a result of those procedures. AHRC, through its website and other information products, is establishing itself as a focal point of AHR information for policy makers, practitioners, patients, offspring born of AHR procedures, researchers and the Canadian public. These information sources will allow Canadians to make more informed decisions related to the use of these technologies.

Performance Analysis

Through its extensive outreach initiatives, the Agency continued to solicit and consider the perspectives and best practices shared by policy makers, practitioners, patients, researchers and Canadians who use or are born of reproductive technologies. In doing so, it extended its national and international networks of experts and agencies involved in the area of assisted human reproduction, while expanding its information offerings through new tools and technology. The Agency is making steady and solid progress toward its goal of serving as Canada's centre of expertise for matters related to assisted human reproduction.

Lessons Learned

Just two years into its mandate, the Agency has actively consulted and considered practices, procedures and standards from national and international experts and organizations working in the rapidly changing field of assisted human reproduction, in order to learn from the experience of its international counterparts, and to inform its planning and development of policies and procedures related to AHR in Canada.

SECTION 3: SUPPLEMENTARY INFORMATION

3.1 Financial Highlights

The financial highlights presented within this Departmental Performance Report are intended to serve as a general overview of AHRC's financial position. The Agency's financial statements can be found on AHRC's website at:

<http://www.ahrc-pac.gc.ca/doc.php?sid=32&lang=eng>

(\$ thousands)

Condensed Statement of Financial Position			
At End of Year (March 31, 2009)	% Change	2009	2008
ASSETS			
Total Assets	(23%)	286	371
TOTAL		286	371
LIABILITIES			
Total Liabilities	(31%)	546	796
EQUITY			
Total Equity	(39%)	(259)	(425)
TOTAL		286	371

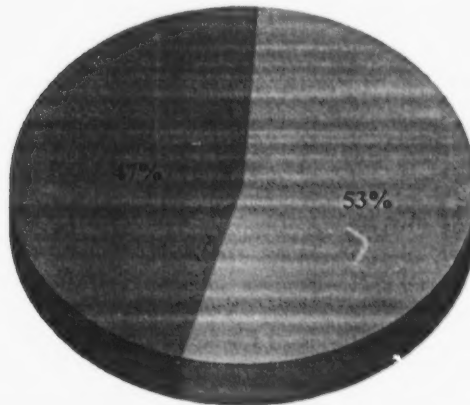
(\$ thousands)

Condensed Statement of Financial Position			
At End of Year (March 31, 2009)	% Change	2009	2008
EXPENSES			
Total Expenses	7%	5728	5309
REVENUES			
Total Revenues		0	0
NET COST OF OPERATIONS		5728	5309

Expenses by Program Activity

The figure below illustrates the breakdown of the Agency's expenses (actual spending) between its two program activities.

Expenses - Where Funds Go



- Health information and knowledge management for assisted human reproduction technologies
- Licensing and enforcement of a regulatory framework for assisted human reproduction technologies

3.2 List of Supplementary Information Tables

All electronic supplementary information tables for the Agency's 2008-2009 Departmental Performance Report can be found on the Treasury Board of Canada Secretariat's website at:

<http://www.tbs-sct.gc.ca/dpr-rmr/2008-2009/index-eng.asp>

Table 8: Sustainable Development Strategy

Table 9: Green Procurement

Table 10: Response to Parliamentary Committees and External Audits

Table 11: Internal Audits and Evaluations, 2008-09

